

### **REMARKS**

Claim 31 has been cancelled, without prejudice.

Claim 27 has been amended to recite "[a]n isolated polynucleotide sequence selected from the group consisting of a polynucleotide that encodes the polypeptide sequence of SEQ ID NO: 3, a polynucleotide that comprises the sequence of SEQ ID NO: 2, and polynucleotide sequences that are at least 95% identical to the sequence of SEQ ID NO: 2." Support for this amendment is found in the specification at, for example, page 6, lines 1-11 and in Examples 1-9. See *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (I) (8<sup>th</sup> ed. Rev. 5, August 2006, pp. 600-92 and 600-84).

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

### **INTERVIEW SUMMARY**

The Examiner is thanked for the courtesies extended during a telephonic Interview conducted with the undersigned on October 31, 2007. During the interview, the foregoing amendments and the pending rejections under 35 U.S.C. § 112 for lack of written description and enablement were discussed. The Examiner agreed that the amendments presented above would place the application in condition for allowance. Therefore, in view of the amendments and remarks below, withdrawal of the rejections and allowance of the claims are respectfully requested.

**§112, First Paragraph Rejections:**

**1. Written Description**

Claims 27, 30, and 33-40 have been rejected under 35 U.S.C. §112, first paragraph. (Paper No. 20070702 at 3). In making the rejection, the Examiner asserted that claims 27, 30, and 33-40 “contain[] subject matter, which was not described in the specification ....” (*Id.*). The Examiner further asserted that “[t]he specification discloses only a single species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.” (*Id.*). The Examiner also asserted that “[t]hese claims are directed to a genus of DNA molecules having 90% sequence identity with SEQ ID NO: 2,” and “[t]he genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins.” (*Id.*). The Examiner then concluded that “one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.” (*Id.*).

Initially, we note that there is a ***strong presumption*** that an adequate written description of the claimed invention is present in an application as filed. See *In re Werthheim*, 191 USPQ 90, 97 (CCPA 1976); and MPEP §2163(II)(A). Further, an applicant may show possession of the claimed invention by describing it using descriptive means such as, for example, words, structures, figures, diagrams and formulas. See MPEP §2163(I). Moreover, a proper written description analysis requires an analysis of the understanding of an ordinarily skilled artisan at the time of the invention. See MPEP § 2163(II)(A)(2); see also *Wang Labs. v. Toshiba Corp.*, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993).

However, with a view towards furthering prosecution, and **as agreed** during the telephonic Interview, independent claim 27 (from which claims 28-30 and 33-40 either directly or indirectly depend) has been amended to recite “[a]n isolated polynucleotide sequence selected from the group consisting of a polynucleotide that encodes the polypeptide sequence of SEQ ID NO: 3, a polynucleotide that comprises the sequence of SEQ ID NO: 2, and polynucleotide sequences that are at least 95% identical to the sequence of SEQ ID NO: 2.”

In view of the foregoing amendment and the agreement reached during the telephonic Interview, it is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

## **2. Enablement**

Claims 27, 30-31, and 33-40 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. (Paper No. 20070702 at 4). In making the rejection, the Examiner acknowledged that the specification is “enabling for the DNA of SEQ ID NO: 2 or a DNA encoding polypeptide of SEQ ID NO: 3 or a DNA encoding a protein having 95% sequence identity with SEQ ID NO: 3 having squalene synthase activity, ....” (*Id.*)

The Examiner, however, asserted that the specification “does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected [to] use the invention commensurate in scope with these [previously presented] claims.” (*Id.*).

Initially, we note it is the Examiner’s burden to demonstrate that a specification is not sufficiently enabling. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA

1971). To carry this burden, the Examiner must identify and clearly articulate the factual bases and supporting evidence that allegedly establish that undue experimentation would be required to carry out the claimed invention. *Id.* at 370. It is well established that claims must be separately analyzed. *Ex parte Jochim*, 11 USPQ2d 561 (BPAI 1988).

However, with a view towards furthering prosecution, and **as agreed** during the telephonic Interview, independent claim 27 (from which claims 28-30 and 33-40 either directly or indirectly depend) has been amended to recite "[a]n isolated polynucleotide sequence selected from the group consisting of a polynucleotide that encodes the polypeptide sequence of SEQ ID NO: 3, a polynucleotide that comprises the sequence of SEQ ID NO: 2, and polynucleotide sequences that are at least 95% identical to the sequence of SEQ ID NO: 2."

In view of the foregoing amendment and the agreement reached during the telephonic Interview, it is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

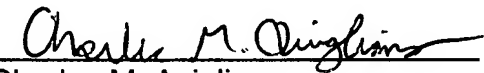
Application No.: 10/528,872  
Amendment Dated: November 28, 2007  
Reply to Office Action Dated: July 31, 2007

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 28, 2007.

  
Charles M. Avigiliano, Reg. No. 52,578

Respectfully submitted,

By:   
Charles M. Avigiliano  
Registration No. 52,578  
BRYAN CAVE LLP  
1290 Avenue of the Americas  
New York, NY 10104-3300  
Phone: (212) 541-2000  
Fax: (212) 541-4630